

L 000007

FEB 28 2000

**510 (k) Summary
Safety and Effectiveness**

This summary of safety and effectiveness information has been prepared in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

Name: Diagnostic Products Corporation
Address: 5700 West 96th Street
Los Angeles, CA 90045

Telephone Number: (310) 645-8200
Facsimile Number: (310) 645-9999

Contact Person: Edward M. Levine, Ph.D.
Director of Clinical Affairs

Date of Preparation: December 27, 1999

Device Name:
Trade: IMMULITE® Carbamazepine and
IMMULITE® 2000 Carbamazepine
Catalog Number: LKCB1 (100 tests), LKCB5 (500 tests)
L2KCB2 (200 tests), L2KCB6 (600 tests)

CFR: A neuroleptic drugs radioceptor assay test system is a device intended to measure in serum or plasma the dopamine receptor blocking activity of neuroleptic drugs and their active metabolites. A neuroleptic drug has anti-psychotic action affecting principally psychomotor activity, is generally without hypnotic effects, and is a tranquilizer. Measurements obtained by this device are used to aid in determining whether a patient is taking the prescribed dosage level of such drugs.

Common: Reagent system for the determination of carbamazepine in serum or heparin plasma.

Classification: Class II device, 91-KLT (21 CFR 862.3645)

Panel: Toxicology

CLIA Complexity Category: We believe the category to be moderate, based on previous classification of analogous tests.

Manufacturer: Diagnostic Products Corporation (DPC)
5700 West 96th Street
Los Angeles, CA 90045-5597

**Establishment
Registration #:** DPC's establishment Registration No. is 2017183

**Substantially Equivalent
Predicate Device:** Abbott TDxFLx Carbamazepine (K904226)

Description of Device: IMMULITE® and IMMULITE 2000 Carbamazepine are solid-phase, chemiluminescent enzyme immunoassays for use with their respective IMMULITE® and IMMULITE 2000 Automated Analyzers.

**Intended Use of the
Device:** IMMULITE® Carbamazepine is a solid-phase, chemiluminescent enzyme immunoassay designed for use with the IMMULITE Automated Analyzer for the quantitative measurement of carbamazepine in serum. It is intended strictly for *in vitro* use in monitoring the therapeutic administration of this drug.

Technology:

This section does not contain any new information for a reviewer who is familiar with the DPC IMMULITE® or IMMULITE® 2000 Systems based upon the review of previous IMMULITE® or IMMULITE® 2000 assay submissions.

IMMULITE® Carbamazepine is a solid-phase, chemiluminescent immunoassay. The solid phase, a polystyrene bead enclosed within an IMMULITE Test Unit, is coated with a polyclonal antibody specific for carbamazepine.

The patient sample and alkaline phosphatase-conjugated carbamazepine are simultaneously introduced into the Test Unit and incubated for approximately 30 minutes at 37°C with intermittent agitation. During this time, carbamazepine in the sample competes with the enzyme-labeled carbamazepine for a limited number of antibody binding sites on the bead. Unbound enzyme conjugate is then removed by a centrifugal wash, after which substrate is added and the Test Unit is incubated for a further 10 minutes.

The chemiluminescent substrate, a phosphate ester of adamantyl dioxetane, undergoes hydrolysis in the presence of alkaline phosphatase to yield an unstable intermediate. The continuous production of this intermediate results in the sustained emission of light, thus

improving precision by providing a window for multiple readings. The bound complex - and thus also the photon output, as measured by the luminometer - is inversely proportional to the concentration of carbamazepine in the sample.

IMMULITE 2000 Carbamazepine is a solid-phase, chemiluminescent immunoassay. The solid-phase, a polystyrene bead, is coated with a polyclonal antibody specific for carbamazepine.

The patient sample and alkaline phosphatase-conjugated carbamazepine are simultaneously introduced into the Reaction Tube and incubated for approximately 30 minutes at 37 °C with intermittent agitation. During this time, carbamazepine in the samples competes with enzyme-labeled carbamazepine for a limited number of antibody binding sites on the bead. Unbound enzyme conjugate is then removed by a centrifugal wash, after which substrate is added and the Reaction Tube is incubated for an additional 5 minutes.

The chemiluminescent substrate, a phosphate ester of adamantyl dioxetane, undergoes hydrolysis in the presence of alkaline phosphatase to yield an unstable intermediate. The continuous production of this intermediate results in the sustained emission of light, thus improving precision by providing a window for multiple readings. The bound complex - and thus also the photon output, as measured by the luminometer - is inversely proportional to the concentration of Carbamazepine in the sample.

Abbott TDxFLx Carbamazepine utilizes fluorescence polarization immunoassay technology in a competitive ligand format. The unlabeled drug (antigen being measured) competes with the fluorescent-labeled antigen for the antibody binding sites. With increasing concentration of unlabeled antigen, more fluorescent-labeled antigen becomes unbound. Therefore, the fluorescent polarization signal decreases as the drug concentration increases, as measured by the fluorometer. Concentrations are determined from a stored standard curve.

Performance Equivalence

Diagnostic Products Corporation asserts that IMMULITE Carbamazepine and IMMULITE 2000 Carbamazepine produce substantially equivalent results to other commercially marketed carbamazepine assays, such as Abbott TDxFLx Carbamazepine. The Abbott TDxFLx Carbamazepine assay utilizes fluorescence polarization technology. Each product is designed for the quantitative measurement of carbamazepine in serum or heparinized plasma. Each product is intended strictly for in vitro diagnostic use as an aid in monitoring the therapeutic administration of this drug.

Method Comparison

The IMMULITE Carbamazepine procedure was compared to a commercially available assay (Abbott TDxFLx) on 47 patient samples, with carbamazepine concentrations ranging from approximately 1.6 to 11 µg/mL. Linear regression analysis yielded the following statistics.

$$(\text{IMMULITE}) = 1.1 (\text{Abbott}) - 0.3 \mu\text{g/mL} \quad r = 0.973$$

Means: 7.3 µg/mL (IMMULITE)
 7.1 µg/mL (TDxFLx)

In a second comparison, the IMMULITE Carbamazepine procedure was compared to Abbott AxSYM on 38 patient samples, with carbamazepine concentrations ranging from approximately 0.7 to 14.7 µg/mL. Linear regression analysis yielded the following statistics.

$$(\text{IMMULITE}) = 1.1 (\text{Abbott}) + 0.12 \mu\text{g/mL} \quad r = 0.972$$

Means: 7.2 µg/mL (IMMULITE)
 6.4 µg/mL (AxSYM)

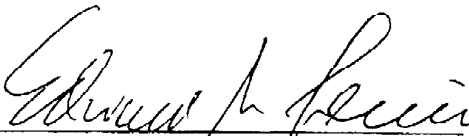
The IMMULITE 2000 Carbamazepine procedure was compared to DPC's IMMULITE Carbamazepine on 97 samples, with carbamazepine concentrations ranging from approximately 1.9 to 16 µg/mL. Linear regression analysis yielded the following statistics.

$$(\text{IML2000}) = 1.0 (\text{IML}) + 0.79 \mu\text{g/mL} \quad r = 0.994$$

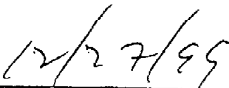
Means: 8.1 µg/mL (IMMULITE 2000)
 7.4 µg/mL (IMMULITE)

Conclusion:

The data presented in this summary of safety and effectiveness is the data that the Food and Drug Administration used in granting DPC substantial equivalence for IMMULITE® Carbamazepine and for IMMULITE® 2000 Carbamazepine.



Edward M. Levine, Ph.D.
Director of Clinical Affairs



Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

FEB 28 2000

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Edward M. Levine, Ph.D.
Director of Clinical Affairs
Diagnostic Products Corporation
5700 West 96th Street
Los Angeles, California 90045-5597

Re: K000007
Trade Name: IMMULITE® Carbamazepine and IMMULITE® 2000 Carbamazepine
Regulatory Class: II
Product Code: KLT
Dated: December 27, 1999
Received: January 3, 2000

Dear Dr. Levine:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

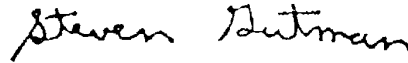
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Device Name: IMMULITE® Carbamazepine and
IMMULITE® 2000 Carbamazepine

IMMULITE® Carbamazepine and IMMULITE® 2000 Carbamazepine are for *in vitro* diagnostic use with their respective IMMULITE and IMMULITE 2000 Analyzers - for the quantitative measurement of carbamazepine in serum or heparinized plasma, as an aid in monitoring the therapeutic administration of this drug.

Jean Cohen
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000007

Concurrence of CDRH, Office of Device Evaluation (ODE)

OR

(Optional Format 1-2-96)